

March 25, 1999

The Honorable Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Henney:

During the past several years, Internet use has evolved dramatically for the purchase of a range of products from airline tickets to investments to almost any item traditionally sold in a store. One group of goods increasingly sold this way includes pharmaceuticals. Ranging from both over-the-counter health aids to actual prescription drugs, many Internet websites now allow consumers using a home computer to purchase pharmaceuticals once only available through a face-to-face visit with a doctor and a pharmacist.

The regulation of pharmacies has traditionally been a state function. States have generally focused on ensuring that pharmacies observe specific guidelines to safely dispense medications to the public, and that they are licensed and operated by qualified and trained staff. State regulators also ensure that any pharmacy under its jurisdiction properly stores and safeguards the pharmaceuticals it sells. The Food and Drug Administration's (FDA) role in regulating pharmaceutical sales is focused generally on ensuring that any drugs sold in the U.S. are FDA approved, properly manufactured, and thus safe and effective. FDA also ensures that all claims and instructions by the drug maker for the product are accurate and not misleading. With the exception of some mail-order operations, because most pharmacies have operated within a local environment (e.g., the corner drug store), this federal-state partnership, for the most part, has been effective in safeguarding public health.

The recent explosion of online sites that both advertise and sell prescription drugs across state and even international lines, may be undermining this regulatory structure. It is not clear who bears the ultimate responsibility for regulating Internet pharmacies, nor is it clear what actions are being taken to ensure that the public is being protected in this new consumer environment. Although some believe that it is mostly the states that are responsible for shouldering most of this burden, the cross-border nature of most Internet sites, coupled with the sheer volume of their activities, may make this an impossible undertaking. The states alone may not have the necessary resources, expertise, or jurisdiction to do this job.

Without a doubt, a host of serious regulatory concerns are posed by Internet pharmacies. For example, as patients are often required to submit personal medical data to an online pharmacy before their prescriptions are processed, highly personal information could be released (accidentally or deliberately) by an online pharmacy without the customer's permission. Some online pharmacies could contribute to the problem of drug interactions, as the traditional face-to-face doctor-patient relationship or pharmacist-patient relationship is replaced by an online computer transaction. Finally, it remains murky how online pharmacies will process (if at all) controlled substances, and not be susceptible to abuse by hackers or other criminal elements. If, as reported, some Internet pharmacies provide prescription drugs without requiring a patient to actually visit a doctor or pharmacist, certain controlled substances could be seriously susceptible to abuse.

Because of our concerns in this area, we would like you to address the following:

(1) What agency or department (at either the state or federal level) does FDA believe is the primary regulator of Internet pharmacies? For this question, please also identify and describe the roles of the other state/federal agencies that may make up this structure.

(2) What specific activities or functions does FDA believe it is responsible for with regard to regulating Internet pharmacies? Please describe both the precise activities now conducted by FDA, and the number

of full-time equivalents (FTEs) dedicated to all identified efforts. Does FDA believe it has enough resources to conduct the activities it presently feels are under its jurisdiction in this regard? If not, what additional resources does FDA require?

(3) Does FDA believe that existing laws and regulations, or the present state/federal regulatory structure, adequately regulate online pharmacy operations? If not, what are the discrepancies, and what changes, if any, does FDA believe must be made?

(4) Please describe FDA's knowledge regarding the differences between existing online pharmacies. For example, some reports suggest that most online pharmacies only fill prescriptions. Other reports, however, have suggested that some actually provide for a doctor consultation (for example, a quick questionnaire is submitted over the Internet, it is reviewed, and then the prescription is then approved and sent directly to the patient without a doctor ever seeing the patient). How prevalent is this latter operation? Do any trends appear in comparing one form of online pharmacy with another?

(5) What is FDA's understanding of how these firms deal with issues such as medical records privacy/protection, the selling of controlled substances, or drug interactions? How serious are these issues and what shortcomings, if any, do online pharmacies have with regard to these issues? Does FDA have any knowledge of how online pharmacies prevent unqualified persons from receiving prescriptions? Are online pharmacies more susceptible to fraud or deception? If so, please explain how?

(6) Finally, what quality issues does FDA believe relate to the methods used to ship online pharmaceutical products, and does FDA believe it has jurisdiction in this area?

Thank you for your cooperation and attention to our request. If you have any additional questions about this matter, please have your staff contact Mr. Christopher Knauer of the Minority staff at (202) 226-3400. We look forward to working with you on this and other important pharmaceutical integrity and consumer protection issues.

Sincerely,

JOHN D. DINGELL
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cc:

The Honorable Tom Bliley, Chairman
Committee on Commerce

The Honorable Michael Bilirakis, Chairman
Subcommittee on Health and Environment

The Honorable Fred Upton, Chairman
Subcommittee on Oversight and Investigations